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Ref: EPR-N

Suzanne Lewis, Superintendent,
Yellowstone National Park
Brucellosis Remote Vaccination Program for Bison DEIS Comments
P.O. Box 168
Yellowstone National Park, Wyoming 82190

Re: CEQ # 20100184; EPA Comments on Brucellosis Remote Vaccination Program for Bison in Yellowstone National Park DEIS

Dear Superintendent Lewis:

The Environmental Protection Agency (EPA) Region 8 has reviewed the Draft Environmental Impact Statement (DEIS) regarding the Brucellosis Remote Vaccination Program for Bison in Yellowstone National Park (YNP). We are providing EPA comments in accordance with our review responsibilities under Section 102(2)(c) of the National Environmental Policy Act (NEPA), 42 U.S.C. Section 4332(2)(c) and Section 309 of the Clean Air Act, 42 U.S.C. Section 7609. Section 309 of the Clean Air Act directs EPA to review and comment in writing on the environmental impacts of any major Federal agency action. EPA's comments include a rating of both the environmental impact of the proposed action and the adequacy of the NEPA document.

This proposed project involves development of a remote vaccination program for bison at YNP. The Final EIS and Record of Decision (ROD) for the Interagency Bison Management Plan (IBMP) prepared in year 2000 indicated that the release of untested bison outside YNP would be linked to the initiation of a remote delivery vaccination program for bison in the Park. This Draft EIS evaluates 3 alternatives for initiation of a Park-wide remote vaccination program: (1) decrease the probability of individual bison shedding Brucella abortus bacteria, (2) lower the brucellosis infection rate of Yellowstone bison, and (3) test, monitor, and adjust for a safe, effective, low-risk, in-Park remote delivery system for vaccination-eligible bison within YNP. Alternative A, the no action alternative, describes the current hand vaccination program using vaccine SRB51 that is intermittently implemented at the Stephens Creek capture facility when hazing of bison becomes ineffective at maintaining spatial separation from private properties north of the park boundary. This alternative relies on capturing bison that move to the Reese Creek boundary area, containing them within the fenced paddocks of the facility, individually

handling each animal, conducting blood tests to determine past exposure to brucellosis, and vaccinating young (calf and yearling) animals by syringe injection. Alternative B includes a combination of the capture program at Stephens Creek and a remote delivery vaccination strategy that would focus exclusively on young, non-pregnant bison. Alternative B would expand the current vaccination program described in Alternative A to include remote delivery of vaccine to young bison throughout Yellowstone National Park so capture and handling of individual animals would not be necessary. Alternative C includes all components of Alternative B, as well as the remote vaccination of adult females. A preferred alternative was not identified in the DEIS, but Alternative C was identified as the environmentally preferred alternative.

EPA recognizes the knowledge and expertise of the National Park Service (NPS) bison management experts, and NPS agency partners involved in implementation of the IBMP (i.e., Animal and Plant Health Inspection Service, U.S. Forest Service, Montana Department of Livestock, Montana Department of Fish, Wildlife, and Parks). Accordingly while EPA is providing our comments, questions, and concerns regarding the DEIS with this letter, we believe it is appropriate to defer to the bison management experts and brucellosis reduction and control experts with the NPS and your partner agencies in regard to how to address bison management and the brucellosis reduction and control issues. However, it is important to both public understanding and NEPA disclosure purposes that the NPS address and respond to EPA's DEIS comments in the Final EIS (FEIS) for this proposed project.

Vaccines Risk to Public Health and Environment

Included among EPA's comments are potential public health concerns regarding possible contact by human handlers or members of the public, including Park visitors, with live brucellosis vaccine. Brucellosis vaccines are characterized as modified live vaccines which have a greater risk of infection by human handlers if appropriate precautions are not taken, and waste associated with vaccines and certain delivery methods could be hazardous to humans and the environment. Brucella abortus is considered a controlled chemical substance or hazardous material under some federal classification systems, and the proposed Strain RB51 vaccine (SRB51) consists of a live culture of these disease causing microorganisms.

While the DEIS states that stringent handling protocols have been developed to address safety concerns and minimize risk to humans from handling *B. abortus* vaccine when implementing the vaccination program, we believe that potential risks to members of the public visiting the Park, other animals besides bison and the environment should be more clearly disclosed. We note that the DEIS states that the remote delivery system using compressed air powered rifles and biobullets containing live vaccine is not designed for high accuracy and long distances like conventional rifles. Consequently, we assume some biobullets may miss their target and be disseminated into the environment where they could come into contact with other animals or the public. The following questions should be addressed in the FEIS: If a biobullet misses its intended target and lands in a stream, lake or wetland area, will dissolution of the biobullet casing release live culture into the aquatic environment? How long are live B. abortus bacteria likely to survive in such environments? Do biobullets or their contents pose a risk to other species if B. abortus bacteria are ingested while still alive or viable?

Also some vaccinated bison will likely migrate to hunting districts where Montana-licensed and tribal hunters harvest a small proportion of the Yellowstone bison population each year. The DEIS states that it takes about 21 days for SRB51 vaccine to clear an animal's system, thus, meat from animals vaccinated with SRB51 should not be consumed at least until after 21 days has elapsed. Since vaccinated bison will be marked by paint ball guns, will such marking be sufficient for bison hunters outside the Park to identify which bison have been vaccinated? Assuming the paint ball marking on vaccinated bison will last well beyond 21 days, how will hunters determine which bison may have been vaccinated within the last 21 days? Is it truly safe to consume meat from a vaccinated bison on the 22nd day after vaccination?

Are there any risks or dangers to animal predators if they consume meat from a vaccinated bison (e.g., wolf, mountain lion, grizzly bear)? We note that the DEIS discusses grizzly bears and wolves, but does not discuss mountain lions. What is the potential for mountain lion infection with brucellosis? What are the dangers to other animals and/or humans should a predator eat meat from a vaccinated bison and then bite another animal or human? The DEIS indicates that many species of mammals, birds, and insects that scavenge bison carcasses may be affected by a vaccination program for bison. Eagles (two species), ravens, magpies, and many other species of smaller perching birds along with coyotes, red foxes, badgers, and numerous carnivorous insects are likely to scavenge on bison carcasses. What are the risks of brucellosis transmission and/or impacts to these other species if they eat meat of a vaccinated bison?

We recommend that the FEIS provide additional information and discussion regarding environmental and public health risks associated with live culture biobullets missing their target and being disseminated in the environment and potentially coming into contact with other animals and Park visitors. The discussion should include additional information regarding the extent to which consumption of meat from untested bison harvested outside the Park may pose a risk to public health, and provide recommendations or guidance to hunters on how to avoid consuming meat from recently vaccinated bison. Additional discussion of the mitigation measures that would reduce risk of hunters eating meat from bison vaccinated with SRB51 is recommended.

Dart delivery of vaccine as an alternative to biobullets was dismissed due to potential liability risks not associated with biobullets (i.e., darts missing targets would be left behind in the ecosystem and would be a bio-hazard, and darts with live vaccine remaining would be an additional safety risk if discovered by uninformed or irresponsible humans). However, it would appear to us that similar bio-hazard liabilities exist with biobullets, although lost darts encountered by humans would pose a greater hazard to skin penetration, but both darts and biobullets contain live B. abortus bacteria that poses a bio-hazard. How long would B. abortus bacteria in the vaccine remain alive or viable in a dart vs. a biobullet that missed its target? Please explain further why biobullet delivery of vaccine is considered less hazardous than dart delivery.

Vaccination of Elk and Cattle

EPA has a concern that potential vaccination of elk and cattle in addition to bison is not thoroughly discussed in the DEIS. The DEIS reports that there were two confirmed cases of hunters (in Montana) contracting undulant fever from elk, with the last confirmed case occurring in 1995. Also, brucellosis transmission from elk to cattle occurred during 2007 and 2008, and the State of Montana and the livestock industry appear more concerned about brucellosis transmission from elk to cattle than from bison to cattle. It would appear, therefore, that detailed consideration of methods and programs to reduce the seroprevalence of brucellosis in bison, without equivalent or at least some consideration of reduction of the seroprevalence of brucellosis in elk, results in ignoring a major source of spread of brucellosis disease, including the disease transmission source that caused recent brucellosis transmissions to cattle in Montana. Among the criteria identified in the DEIS for implementation of an effective vaccination program is that that all possible routes of re-infection be evaluated, treated, or effectively separated from the vaccinated population; and it is stated that the potential for elk to maintain the disease and re-infect susceptible bison cannot be disregarded.

It is also not clear why the DEIS does not include much discussion of vaccination of cattle as a means to reduce potential for infection of cattle with brucellosis. The DEIS notes that the risk of brucellosis transmission could be reduced by vaccination of cattle as well as bison. It would appear that vaccination of cattle would be much easier than vaccination of wild bison. The DEIS indicates that a brucellosis vaccine and diagnostics workshop was held by the U.S. Animal Health Association in August, 2005, and experts in vaccine development, disease diagnostics, and vaccine delivery systems recommended that managers dramatically increase the use of established brucellosis vaccines in elk, bison, and cattle in the Greater Yellowstone Ecosystem (GYE), and recommended that research scientists move forward with experiments to evaluate the effectiveness of novel existing vaccines in cattle, bison and elk.

It appears to EPA, therefore, that the DEIS should provide additional discussion and consideration to methods or programs that would reduce disease transmission from elk to cattle, and increase cattle immunity via cattle vaccination. The minimal information about this topic is a shortcoming in the DEIS. EPA recommends that the FEIS include additional discussion of vaccination of elk and cattle in addition to vaccination of bison to reduce seroprevalence of brucellosis in all three species.

Availability of Safer and More Reliable Vaccines

EPA also notes that many uncertainties are discussed in the DEIS in regard to implementation of the remote vaccination program for bison (e.g., duration of immunization protection provided by Strain RB51 vaccine (SRB51) is not fully known; brucellosis diagnostic methods applied to wildlife need to be validated; oral and remote ballistic delivery methods, including achieving sustained release need to be improved; effective bio-markers to evaluate vaccine delivery, improve vaccine stability and storage/shelf life, and optimize vaccine dosage need to be created; a rapid assessment protocol to screen additional promising vaccine candidates needs to be developed; effectiveness of vaccine delivery before widespread application of vaccination programs needs to be developed; biobullet encapsulation to make effectiveness of

biobullet immunization similar to syringe vaccination needs to be developed; etc.).

Also, the proposed vaccine SRB51 is stated to be imperfect in that it does not offer protection from B. abortus infection, but provides intermediate protection (~80%) from B. abortus transmission. The B. abortus bacteria can evolve adaptive strategies to survive by evading antibody attacks and through genetic changes in their chemistry that lead to successful natural selection processes. These aspects of SRB51 could result in SRB51 vaccination becoming ineffective, leading to an increase in transmission potential, stronger persistence within the bison host, and greater pathogenicity (i.e., virulence or degree of intensity of the disease produced by a pathogen).

The DEIS also discusses advantages of DNA vaccines and killed vaccines over the live vaccines (SRB51) proposed for use in this project. DNA vaccines and killed vaccines appear to offer great promise for reducing risks associated with the remote vaccination program as well as reducing costs for the program. The DEIS indicates that the goal of developing a low risk and effective DNA or other type of killed vaccine for brucellosis in wildlife seems attainable, although this technology is still being developed, and it is likely that over time new methods will result in more efficient delivery to the same number or a higher percentage of eligible bison, and that vaccine technology will evolve to produce improved vaccines that are lower risk for human handling and more efficient at conveying an acquired immune response.

Given the uncertainties and risks, perhaps it would be prudent to defer implementation of the remote vaccination program until uncertainties and risks can be reduced, and improved vaccines that are lower risk for human handling and more efficient at conveying an acquired immune response are available. We note that the proposed remote vaccination program with SRB51 vaccine is to be implemented over a 30 year period, and it may take 5 to 20 years to detect significant changes in seroprevalence following vaccination with SRB51, and a period of 15-20 years of implementation and monitoring may be required to determine how well remote vaccination program goals have been met. Also, the DEIS states that brucellosis will remain a concern for the livestock industry regardless of the outcome of a remote delivery vaccination program for Yellowstone bison and, thus, such a program would likely have negligible impacts on social and economic factors affecting the livestock industry. It appears, therefore, that a short delay in implementing the program may not be too significant over the long term. If the NPS decides to proceed with remote vaccination using SRB51 at this time, it certainly appears appropriate for the NPS to modify the vaccination program to use DNA vaccines or other killed vaccines as improved vaccine technology becomes available.

Injury to Target Animals

It would be helpful to public understanding to describe the extent to which a "biobullet" will penetrate bison hair/hide, and cause any other potential impacts or injuries or trauma to target animals. While the DEIS indicates that periods of extremely cold temperatures would be avoided to minimize stress to bison during difficult time periods during winter when energy conservation is important (page 37), it would appear that the long cold winter season in Yellowstone National Park during normal winter conditions may stress bison. Would bison recover better from biobullet shooting trauma if shooting did not occur as late as November,

since difficult winter weather can occur in Yellowstone Park as early as November? Would use of a dart to deliver vaccine to a bison result in less shooting trauma to the bison?

EPA agrees with the NPS that monitoring and adaptive management are appropriate to use where impacts may be uncertain and future monitoring is necessary to identify actual impacts and to make adjustments in subsequent actions or implementation decisions based on monitoring results. We support development of a Surveillance Plan for monitoring the effects and effectiveness of vaccination in Appendix H.

Based on the procedures EPA uses to evaluate the adequacy of the information and the potential environmental impacts of the proposed action and alternatives in an EIS, the Brucellosis Remote Vaccination Program for Bison DEIS has been rated as Category EC-2 (Environmental Concerns - Insufficient Information). The EPA's environmental concerns regard potential public health effects associated with implementation of the remote vaccination program, and uncertainties and risks associated with the program. A summary of EPA's DEIS rating criteria is attached.

We appreciate the opportunity to review this Draft EIS and offer our comments. If you have any questions please contact me at 303-312-6004, and in addition you may contact Mr. Stephen Potts in our EPA Region 8 Montana Office in Helena at 406-457-5022 or in Missoula at 406-329-3313. Thank you for your consideration.

Sincerely,

Larry Svoboda
Director, NEPA Program
Office of Ecosystem Protection and Remediation

Enclosure

cc: Julie A. DalSoglio/Stephen Potts, EPA Region 8 Montana Office, Helena